IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, *Plaintiffs*, vs. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON, *Defendants*.	:	Civil Action No. 19-12107 (MEF) (SDA) *Document electronically filed*

REPLY BRIEF OF RELATOR ZACHARY SILBERSHER OBJECTING TO SPECIAL MASTER ORDER (ECF 422) RELATED TO *IN CAMERA* REVIEW OF DOCUMENTS PURSUANT TO THE CRIME-FRAUD EXCEPTION

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INTRODUCTION

Defendants make four points in their opposition ("Opp.") to Relator's objection to the Special Master's order (ECF 422). They each fail.

First, Defendants argue that Relator fails to identify any legal or factual errors in the Special Master's analysis. But the Special Master's order contains no legal or factual analysis, and Relator has no access to the documents reviewed. Rule 53 requires *de novo* review of the Special Master's decision, which necessarily entails a *de novo* review of the underlying documents.

Second, Defendants claim that *In re Abbott Lab'ys*, 96 F.4th 371 (3d Cir. 2024), is inapposite because, in that case, the court had already determined that sham litigation had occurred. This is a distinction without a difference. Proof of the underlying fraud is not required for the crime-fraud exception to apply—only a *prima facie* showing is required. Relator has provided extensive *prima facie* evidence of fraud. (*See* ECF 394; ECF 395 & 395-1 through -6)

Third, Defendants rehash their discredited argument that Relator's motion is untimely and overbroad that they raised when opposing *in camera* review (ECF 345, at 28-29; ECF 414, at 28-30). This Court implicitly rejected those arguments when it ordered *in camera* review. (ECF 417). Defendants' objections, besides being meritless (*see* ECF 363, at 11-12), are also irrelevant to a *de novo* review of the Special Master's decision *after* conducting the *in camera* review.

Fourth, Defendants dispute Relator's *prima facie* showing of fraud (by incorporating arguments from their prior brief, ECF 414).[1] Defendants' primary defense is that their commercial

[1] Defendants say that Relator should not be able to incorporate the points he raised in his prior brief requesting *in camera* review so as to circumvent page limits. That is not the case here. Relator's moving brief was only 14 pages, well below the 30-page maximum; and the facts that Relator relies upon to demonstrate a *prima facie* case of fraud are based on the documents set forth in the supporting Declaration of Bruce D. Greenberg dated October 25, 2024 and its exhibits (ECF 395 & 395-1 through -6). Moreover, the facts summarized in ECF 394 provided the bases for Relator's request for *in camera* review and demonstrate a *prima facie* case of fraud, which the Court considered when it ordered *in camera* review (ECF 417).

success argument could not be fraudulent because, even though they believed prednisone co-administration was a marketing challenge, they always believed in its therapeutic efficacy. This argument is repeatedly belied by Defendants' own internal documents.

Among other things, those documents show: (i) Defendants believed that prednisone co-administration was a primary *weakness* for the drug's success against competitors; (ii) Defendants doubted the therapeutic efficacy of prednisone co-administration—in fact, the purpose of prednisone coadministration was to avoid side effects, and not for therapeutic efficacy; (iii) after the drug launched, but before the patent was granted, Defendants tested alternatives to prednisone co-administration; (iv) Defendants knew that Zytiga's closest competitor, Xtandi, was more therapeutically effective and held the competitive advantage because it did not require prednisone; and (v) Defendants believed Zytiga's commercial success was attributable to numerous factors unrelated to the invention in the '438 patent. None of these were disclosed to the Patent Office.

More importantly for the purposes of the current motion, even if Defendants dispute this evidence, it does not undermine Relator's *prima facie* showing of fraud. As noted by Relator in his moving brief—which was not refuted by Defendants in opposition—the standard for invoking the crime-fraud exception is not a demanding one, and fraud is not required to be proven even by a preponderance of the evidence. (ECF 424-1, at 10, *citing In re Grand Jury*, 705 F.3d 151, 153-54 (3d Cir. 2012) ("the party opposing the privilege is not required . . . even to show that it is more likely than not that the crime or fraud occurred.")).

ARGUMENT

I. Relator is entitled to *de novo* review of the 50 priority documents.

Defendants say that Relator fails to identify any legal or factual error in the Special Master's review. (Opp. 7). However, the Special Master's order contained no legal or factual

analysis (*see* ECF 422). This is not surprising given the nature of the Special Master's decision—namely, *in camera* review of documents Relator has not seen and, therefore, the Special Master cannot directly discuss.

A court reviews the factual findings and legal conclusions of a Special Master *de novo*. Fed. R. Civ. P. 53(f)(2)-(3). In this context, such review necessarily requires the Court to review the documents themselves, and Defendants cite nothing to the contrary. Under Defendants' logic, a decision on *in camera* review that contains no analysis—because it *cannot* contain any direct analysis—can never be appealed.

II. *Abbott Laboratories* is on point.

Defendants attempt to distinguish *Abbott* on the ground that the district court in that case had already held that the underlying patent lawsuit was a "sham," whereas no court has made that same finding here. (Opp. 9). That is a distinction without a difference. This Court has implicitly determined—in the course of ordering the *in camera* review—that Relator has established a "factual basis to support a good faith belief by a reasonable person that *in camera* review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies." *United States v. Zolin*, 491 U.S. 554, 572 (1989); *see also* ECF 394, at 6-11.

Defendants argue that the '438 patent could not have been fraudulent because, when it was invalidated, Judge McNulty stated that his ruling on invalidity of the '438 patent was "a judgment call." (Opp. 9). Defendants misconstrue the Court's decision. The ruling did not address Relator's allegations in this case, which survived a motion to dismiss. *See United States. v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212 (D.N.J. 2021) (McNulty, J.). Moreover, the Patent Trial and Appeals Board ("PTAB") determined the invalidity of the '438 patent in three separate *inter partes* review ("IPR") proceedings, which were affirmed by the Federal Circuit. In total, five separate

proceedings have ruled the '438 patent is invalid *and* Defendants' commercial success argument to the Patent Office was false.[2] If Defendants' commercial success argument were "true," as Defendants claim (see Opp. 9), then the courts and the PTAB would not have rejected it.

Defendants also misconstrue Judge McNulty's statement that "this abiraterone product has enjoyed commercial success." (Opp. 10, citation omitted). It is undisputed, as Judge McNulty acknowledged, that Zytiga has made billions of dollars in revenue. That is only half the story. Defendants committed fraud when they attributed that "success" to the claimed invention (*i.e.*, prednisone coadministration), knowing that such success occurred *despite* the necessity of co-administering prednisone. Defendants also made material omissions by failing to disclose the *actual* reasons they knew were responsible for the drug's sales, such as the efficacy of the underlying drug, Defendants' exclusive license to a blocking patent, and the fact that Zytiga's competitors did not obtain FDA approval until much later. Judge McNulty did *not* find that Defendants' commercial success argument supported non-obviousness for the '438 patent, or that there was the required nexus between commercial success and prednisone coadministration. Had he done so, he would not have invalidated the patent. *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 387 (D.N.J. 2018).

Defendants also claim that Judge McNulty ruled that Defendants' assertion of the '438 patent in litigation was not fraudulent. (Opp. 9). That is not true. Defendants do not tell this Court that, while Judge McNulty dismissed a separate antitrust action for sham litigation related to the '438 patent, he specifically noted that the antitrust plaintiffs did not plead fraud on the Patent

[2] *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019); *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352, 386-87 (D.N.J. 2018); *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, 2018 WL 454509, at *18 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332, 2018 WL 456305, at *18 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio AG v. Janssen Oncology, Inc.*, IPR2016-01582, 2018 WL 456328, at *21 (P.T.A.B. Jan. 17, 2018).

Office—*i.e.*, the claim Relator has made in this case. *See La. Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, No. 19-cv- 14146-KM, 2021 WL 4988523, at *17 n.21 (D.N.J. Oct. 27, 2021) (noting that "the plaintiffs are walking a tightrope. The patent did issue, and they specifically disclaim a *Walker Process* theory that Janssen committed fraud on the PTO.").

Defendants also note that no court or party previously raised an inequitable conduct defense to the '438 patent. (Opp. 10 n.3). That is not surprising. Fraud arguments, including inequitable conduct, cannot be raised in IPR proceedings. *See* 35 U.S.C. § 311(b) (an IPR petitioner can seek to invalidate a patent "only on the basis of prior art consisting of patents or printed publications"); *see also Cellwitch Inc. v. Tile, Inc.*, No. 19cv1315, at *3-4 (N.D. Cal. Nov. 2, 2023). Further, generics are not incentivized to raise inequitable conduct defenses in Hatch-Waxman litigations for multiple reasons. Proving a patent is invalid accomplishes the same result (freedom to operate) without the heightened standard of proof to show fraud and specific intent. *See Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011).[3]

Finally, Defendants argue that frivolous legal claims or arguments cannot be fraudulent. That is not true, because "the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 191 (2015); *cf. e.g.*, *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1117 (9th Cir. 2020) (explaining that the FCA does not "carve out an exception for clinical judgments and opinions"). The cases Defendants rely upon do not support their extreme view, but hold only that, in those specific instances, there was no evidence of fraud.

[3] By contrast, Relator does not allege inequitable conduct in this case, but rather alleges fraud under the FCA, which does not require specific intent. 31 U.S.C. § 3729(b)(1)(B).

See Oxxford Clothes XX, Inc. v. Expeditors Int'l of Wash., Inc., 127 F.3d 574, 577 (7th Cir. 1997) (holding that Expeditors' claim was frivolous, but not fraudulent, because "Expeditors did not misrepresent any fact"); *In re EEOC*, 207 F. App'x 426, 434 (5th Cir. 2006) (holding crime-fraud exception inapplicable because the only evidence of fraud was continuing a frivolous litigation); *In re St Johnsbury Trucking Co.*, 176 B.R. 122, 125 (S.D.N.Y 1994) (finding no fraud on the court occurred because there was no evidence that Bankers concealed evidence of its knowledge of the location of the receivable records). In contrast, Relator has submitted extensive evidence of fraud *other than* assertion of frivolous claims or arguments, such as false statements concerning the reasons for Zytiga's commercial success as resulting from prednisone coadministration or material omissions of fact. (S*ee* ECF 394, at 4-11 & 20-26; *infra* Section IV).

Critically, Defendants fail to refute, and therefore concede, that for Relator's FCA claims, Relator is not even required to show Defendants' actual knowledge, because if Defendants were "conscious of a substantial and unjustifiable risk" that their statements to the Patent Office were false but submitted them anyway, FCA liability attaches. (*See* Mot., ECF 424-1, at 12, citing *United States ex rel. Schutte v. SuperValu Inc.*, 589 U.S. 739, 749 -51 (2023)). This case is therefore *a fortiori* to *Abbott*, which was premised on a sham litigation theory having stringent standards requiring actual knowledge that the litigation was objectively baseless.

III. Relator's request is timely and reasonable.

Defendants' third point makes a number of inaccurate arguments. They first contend that Relator's request is untimely (Opp. 11). This simply repeats what Defendants unsuccessfully argued when opposing *in camera* review in the first place (ECF 345, at 28-29; ECF 414, at 28-30). In ordering an *in camera* review, this Court implicitly rejected that argument. (ECF 417). Defendants' objections are also wrong, as explained in ECF 363, at 11-12. Defendants caused the

delay because of their insistence that resolution of privilege issues should have been postponed until after fact depositions concluded to "see how the privilege issues play out." *Id.* In any event, these timeliness objections are irrelevant to the current motion that seeks review of the Special Master's *in camera* review.

Defendants also complain that Relator's request is too broad (Opp. 11). Yet, there is no dispute that Relator narrowed the request to 50 documents to alleviate the Court's burden. If those documents reveal evidence of "furtherance of fraud," it is reasonable for the scope of *in camera* review to be broadened to the 200 promising documents that Relator identified—the same number that the district court reviewed in *Abbott*, 96 F.4th at 377—out of over 2,400 withheld documents. (Mot., ECF 424-1, at 1 & 14)[4] Relator has selected "a critical time period when counsel and management were determining whether their fraudulent patent should be listed in the Orange Book, which would trigger Hatch-Waxman lawsuits in which Defendants would assert the '438 patent, delaying entry generic entry for years." (ECF 424-2 at 12).

Finally, Defendants complain that Relator's opening brief (ECF 424-2) identified six categories of documents that should be produced if uncovered during the *in camera* review. (Opp. 11) Relator described those categories to assist the Court's review by illustrating the types of

[4] Defendants say that Relator is asking the Court ultimately to review 965 documents. (Opp. 7) That substantially inflates what Relator *actually* requests. (Mot., 1 & 14) The fact that Defendants have withheld a large number of documents should not shield them from scrutiny, or defendants would be rewarded for making improper, blanket privilege designations.

Defendants also incorrectly say that Relator is relying on or revising new theories of liability that "fall outside the claims set forth in Relator's pleading." (Opp. 2, 6) That accusation is simply untrue, which can be easily verified by comparing Judge McNulty's description of Relator's claims in denying Defendants' motion to dismiss in 2021, with what Relator describes in his brief. *Compare, Janssen*, 576 F. Supp. 3d at 217-22 & 227-32 *with* Mot., ECF 394, at 4-7. Of course, during discovery, Relator has obtained substantial evidence supporting his theories of liability and confirming the complaint's allegations.

Defendants incorrectly assert that "Relator failed to meet the evidentiary standard for *in camera* review in the first place." (Opp. 2) That cannot be true, because this Court ordered *in camera* review. (ECF 417)

documents that would be subject to the crime-fraud exception based on the guidance provided by the Third Circuit in *In re Abbott*, and previously specified by Relator in ECF 424-1, at 13-14 (*citing* the corresponding sections in ECF 394). They are not *new* requests.

IV. Relator has made a *prima facie* showing of fraud on the Patent Office.

Defendants' opposition brief incorporates by reference their prior arguments disputing Relator's fraud allegations. (Opp. 6, incorporating arguments from ECF 414). Those arguments fail to undermine Relator's *prima facie* case.

One of Relator's theories of fraud is that Defendants procured the '438 patent by making affirmative misrepresentations and misleading omissions to the Patent Office. The Patent Office repeatedly rejected Defendants' patent claims calling for the coadministration of prednisone with abiraterone acetate (the active ingredient in Zytiga), because that combination was already taught by the prior art. The Patent Office granted the patent only after Defendants misrepresented that Zytiga's commercial success resulted from prednisone coadministration, thus purportedly demonstrating non-obviousness. For commercial success to justify patentability, a nexus must exist between the unique, inventive features of a patent and the product's commercial success. *See Brown, & Williamson Tobacco Corp. v. Philip Morris Inc.,* 229 F.3d 1120, 1130 (Fed. Cir. 2000). Relator has provided evidence that Defendants' documents demonstrate that Defendants knew prednisone co-administration was *not* the reason for Zytiga's commercial success, and that Defendants withheld the actual reasons they knew to be responsible for such success.

The strongest proof of this is that Defendants' internal documents repeatedly reveal that they believed that prednisone was a *weakness* for Zytiga's commercial success. (*See* ECF 394 at 6-10; *e.g.*, ECF 395, Ex. 8, at 3 [redacted]

[redacted]). In other words, Defendants believed the drug was successful *despite* prednisone co-administration, not because of it—*i.e.*, the exact opposite of what they told the Patent Office to acquire the '438 patent.

The evidence is so overwhelming (*e.g.*, ECF 394, at 6-10) that Defendants do not even attempt to dispute they believed prednisone co-administration was a *weakness*. Rather, they euphemistically claim they believed prednisone co-administration may have been a "marketing challenge," but they believed in its "therapeutic efficacy." (ECF 414 at 18). The evidence shows otherwise. [redacted] Defendants expended tremendous resources in conducting these studies precisely because they knew prednisone co-administration was a hindrance to Zytiga sales. Defendants withheld this information from the Patent Office. If Defendants believed that prednisone co-administration was integral to Zytiga's success, they would not have run studies seeking to mitigate or eliminate it.

Even if Defendants did believe in the therapeutic efficacy of co-administering prednisone with Zytiga—which they did not—additional evidence still shows fraud. Defendants' documents are rife with admissions that they believed Zytiga succeeded for reasons other than prednisone co-administration, including: the efficacy of abiraterone compared to legacy treatments; first mover advantage against competing treatments, such as Xtandi; and the fact that U.S. Patent No.

5,604,213 (the '213 patent) was a blocking patent for Zytiga (ECF 394 at 7, 9-11).[5] As further proof, Defendants' internal documents demonstrate that Defendants positioned and marketed Zytiga against their principal competitor, Xtandi, for reasons having nothing to do with the purported therapeutic efficacy of prednisone coadministration. (*See* ECF 395, Ex. 7 at 11)

Defendants go so far as to discount the efficacy of Zytiga's active ingredient (as opposed to prednisone coadministration) to its commercial success (*See* ECF 414, at 19). On its face, this is baseless—one of the largest pharmaceutical companies in the world is claiming that its blockbuster drug, Zytiga, was *not* commercially successful primarily because of the efficacy of a new compound (abiraterone acetate), but rather because the drug must be taken with a steroid to treat side effects. Moreover, Defendants in fact believed that coadministration was a *weakness* compared to competing drugs that did not require prednisone co-administration. (*Supra*, at 8-9 & ECF 394, at 6-11) Simply put, an important reason for Zyiga's success is because abiraterone acetate was the first effective treatment in decades. Prednisone coadministration was required to treat side effects; it was not intended to, and in fact did not enhance, the drug's therapeutic efficacy. There is absolutely no evidence to support that proposition; it's not true; and Defendants never believed it to be true.

In fact, the PTAB conclusively determined that the efficacy of abiraterone acetate (the active ingredient in Zytiga)—as opposed to prednisone coadministration—was primarily responsible for the drug's commercial success. *See Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 86 at 41 (P.T.A.B. Jan. 17, 2018) (finding no nexus to support commercial success evidence of non-obviousness because "the record evidence attributes Zytiga's

[5] Defendants previously suggested that Relator conceded that Defendants disclosed these "actual reasons" for Zytiga's commercial success during prosecution of the '438 patent (ECF 354 at 19). That is false (*see* ECF 364 n.2). More importantly, the prosecution files of the '438 patent, including the commercial success argument, speak for themselves (*see* ECF 345-1, Ex. 2).

commercial success to abiraterone acetate, *rather than* to the combination of abiraterone acetate and prednisone") (emphasis added). Defendants' current argument that they believed Zytiga's therapeutic efficacy resulted from the claimed invention (prednisone coadministration) is an after-the-fact justification that nobody believed when Defendants filed their patent application. And the Federal Circuit, along with this Court and the PTAB, have rejected Defendants' commercial success argument, which was not even made on this basis.[6] Therefore, the only factual question for the jury to decide is whether Defendants knew their statements supporting their commercial success argument were false, or were reckless or deliberately indifferent in stating them. Relator has provided a *prima facie* case that this is so. (*See, e.g.*, ECF 394, at 4-18 & 20-27)

There is a reason why Defendants refuse to acknowledge the basic truth that Zytiga's *active ingredient* was principally responsible for Zytiga's commercial success, as opposed to prednisone administration. Doing so would have been fatal to the '438 patent application, because the chemical compound for abiraterone acetate was already patented by the '213 patent, which issued long before the '438 patent (and is therefore prior art). This alone destroys Defendants' good faith belief in nexus, because "[i]f commercial success is due to an element in the prior art, no nexus exists." *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006).

Defendants also argue that because the FDA label requires coadministration with prednisone, it was "entirely reasonable for J&J to argue that Zytiga's significant sales provided

[6] Defendants never relied on the supposed therapeutic efficacy of prednisone coadministration in supporting their false commercial success argument to the Patent Office. Instead, the prosecution history demonstrates that Defendants' only argument for why a nexus existed between the '438 patent's claimed invention (prednisone coadministration) and the drug's commercial success, was that the FDA label for Zytiga required prednisone coadministration—the purpose of which was to address potential side-effects and had nothing to do with enhancing the drug's therapeutic efficacy. (ECF 345-1, Ex. 2 at ZYTIGA_LIT_05384890-91)

evidence that the co-administered formulation was not obvious." (ECF 414, at 19). That is not the law—nexus is not established simply by showing that claimed invention is covered by an FDA-approved indication. *See AstraZeneca LP v. Breath, Ltd.*, 603 F. App'x 999, 1001-02 (Fed. Cir. 2015) (rejecting commercial success nexus for patents related to sterility even though sterility was required for FDA approval); *see also Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1330 (Fed. Cir. 2017) (rejecting nexus argument on the basis that drug was first solid oral dosage form for MS that received FDA approval).[7] In any event, the scienter inquiry does not end merely because a defendant can concoct a "reasonable" justification for its false claims after the fact; instead, it requires an inquiry into Defendants' "knowledge and subjective beliefs." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023). This is exactly why the Court must review Defendants' documents.

Defendants' argument is also wrong because the law does not permit a patent applicant to argue commercial success in favor of patentability based on an FDA-approved indication, but then fail to disclose other reasons the applicant knows were responsible for driving commercial sales. If a patent applicant is aware of other factors driving sales, they cannot be concealed from the Patent Office. 37 C.F.R. § 1.56(b) (the affirmative duty of candor on patent applicants to disclose information "material to the patentability of a claim" includes any information that "refutes, or is

[7] Indeed, if Defendants' interpretation were the law, then any patent application reading upon an FDA-approved indication that showed commercial success would necessarily be patentable. Settled law holds otherwise—the fact that a product is covered by the patent is insufficient to show nexus. *Merck & Co. Inc. v. Teva Pharmaceuticals USA Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Instead, the claimed invention must be the primary reason driving commercial success. *See Qualtrics Labs, Inc. v. OpinionLab, Inc.*, IPR2014-00421, Paper 41, at 30-31 (P.T.A.B. July 24, 2015) (nexus requires proving "the sales were a *direct result* of the *unique characteristics* of the invention, and *not* a result of economic commercial factors unrelated to the quality of the patented subject matter.") (emphasis added). Simply showing that a patent covers a product that works as intended and made lots of money is insufficient. *See J.T. Eaton & Co. v. Atl. Paste & Glue Co.,* 106 F.3d 1563, 1571 (Fed. Cir. 1997).

inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability."). Defendants did not comply with this obligation. Defendants' own documents (and deposition witnesses) repeatedly discuss the multitude of reasons Zytiga was successful that had nothing to do with prednisone, such as the efficacy of abiraterone compared to legacy treatments; Zytiga's first mover advantage against competing treatments, such as Xtandi; and Defendants' exclusive license to a blocking patent, namely, the '213 patent (ECF 394 at 7, 9-11). Defendants failed to disclose any of these factors that they knew about to the Patent Office. (ECF 345-1, Ex. 2 at ZYTIGA_LIT_05384890-91).

In addition to disputing their fraud, Defendants claim their withheld communications cannot be "in furtherance" of the fraud because, at worst, they purportedly show only that Defendants' lawyers "lacked faith in the success of the '438 Patent in litigation." (ECF 414 at 28). But if the emails show that Defendants' lawyers doubted that they could successfully assert the '438 patent against generic competitors (because the commercial success representations to the Patent Office were false) but nevertheless listed the patent in the FDA's Orange Book (which required a certification that the patent could reasonably be asserted against generic competitors, *see* ECF 394, at 17; 21 C.F.R. 314.53(b)) and then asserted the patent against generic competitors in patent litigation, those are precisely the types of emails deemed to be "in furtherance of the fraud" under *Abbott*.

Defendants also suggest that communications with counsel after the '438 patent issued cannot themselves be "in furtherance" of the fraud alleged in this case, because Defendants never submitted any internal planning documents to the Patent Office or any government healthcare program (ECF 414, at 28). That misconstrues the scope of the "in furtherance" requirement for the crime-fraud exception. In *Abbott*, the emails indicated a reasonable basis to suspect the defendants

"intended to file a sham litigation for the purpose of preventing" generic entry. *Abbott*, 96 F.4th at 383. Discussions among Defendants and their counsel that filing the '438 patent could delay generic entry would fall under the crime-fraud exception for the same reasons they did in *Abbott*. The fraud in this case did not end once the '438 patent issued. Instead, Defendants' actions—planned and primarily implemented by their in-house counsel—such as listing the '438 patent in the Orange Book, and then asserting it in litigation to delay generic entry, were "in furtherance" of that fraud. It doesn't matter whether the withheld communications were submitted to the Patent Office or any other government agency.

Defendants contend that their withheld communications demonstrate only prudent business judgment. Defendants admit, however, that in 2015, *after the '438 patent issued*, they contemplated a loss of exclusivity ("LOE") for Zytiga starting in July 2017, nearly 10 years before it was scheduled to expire were the patent valid. (ECF 414, at 27). Defendants claim this was because "[a]ll litigation involves the risk of variable outcomes." *Id.* But that is exactly what the *in camera* review is intended to confirm or deny. If Defendants' internal communications reveal counsel doubted they could defend the '438 patent's validity or the commercial success argument, and Defendants planned for generic entry when they expected the courts to invalidate the '438 patent, then those communications or supporting analyses would be in furtherance of a fraud under *Abbott*. Indeed, Defendants' commercial success argument was rejected, and the patent was invalidated near the time Defendants' LOE models predicted.

Defendants cite to *In re Neurontin Antitrust Litig.*, 801 F. Supp. 2d 304 (D.N.J. 2011), but in that case, the court rejected *in camera* review because the purported "crime" (off-label promotion) was unrelated to the subject of the emails (assertion of an unrelated patent). Here, Relator seeks communications that relate directly to the "fraud," namely, Defendants' decision

to assert a patent that was itself procured through fraud. *Neurontin* also pre-dates *Abbott*, which is binding upon this court as to the scope of the "in furtherance" test.[8] Defendants also cite to *In re Richard Roe, Inc.*, 68 F.3d 38 (2d Cir. 1995), which is an out-of-circuit decision that likewise pre-dates *Abbott*. Regardless, *Roe* is inapplicable because the court applied an incorrect test—namely, the "relevance" test, rather than an "in furtherance test," and one of the privilege holders was acknowledged to be innocent.

CONCLUSION

For the foregoing reasons, Relator respectfully objects to the Special Master's Order (ECF 422). The Court should conduct a *de novo* review of the 50 priority documents it previously ordered the Special Master to review *in camera* to determine if any fall under the crime-fraud exception under *Abbott*. If the Court determines that any of the 50 priority documents fall under the crime-fraud exception; or if review of the 50 priority documents suggest crime-fraud communications likely exist among the other 200 documents identified by Relator, the Court should order review of those documents as well.

[8] The Special Master also relied upon *In re Neurontin* to deny *in camera* review in the first instance (ECF 374 at 15). The Special Master distinguished that case on the ground that Pfizer pled guilty to illegal conduct, whereas here, Defendants dispute Relator's allegation of fraud. From there, the Special Master found that because the parties still dispute the underlying fraud in this case, that counsels against *in camera* review to determine application of the crime-fraud exception. (*Id.*). But the application of the crime-fraud exception does not require proof of the underlying fraud or crime, only a *prima facie* showing. *In re Grand Jury*, 705 F.3d at 155.

The Special Master also found that Defendants "fairly dispute" whether the actual reasons of Zytiga's commercial success were disclosed to the Patent Office. Yet, that "fair dispute" (located at ECF 354 at 19) amounts to a dispute whether disclosure of a license for the '213 patent is tantamount to disclosing that the '213 patent was *exclusively* licensed a blocking patent, It is not. Regardless, the required *prima facie* showing of fraud is not undermined even if the opposing party merely disputes it.

LITE DEPALMA GREENBERG & AFANADOR, LLC

Dated: March 31, 2025

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